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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,069	01/29/2002	Alejandro Abuin	LEX-0305-USA	6633
24231	7590	04/06/2004	EXAMINER	
LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160			KELLY, ROBERT M	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/19

## Office Action Summary

Application No.

10/060,069

Applicant(s)

ABUIN ET AL.

Examiner

Robert M Kelly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claim 8 is currently pending and considered.

#### ***Claim Rejections - 35 USC § 112***

##### **Rejections under 35 USC § 112, second paragraph**

The rejection of Claim 8 pertaining to the recitation of the term “first disclosed” has been withdrawn in view of Applicant’s amendments and arguments.

Applicant's arguments filed 13 February 2004 have been fully considered but they are not persuasive.

Claim 8 remains rejected for the term “an engineered mutation ... comprising a polynucleotide sequence ...” for reasons of record set forth in the office action of 8 September 2003. This rejection is traversed by Applicant, by stating that those of skill in the art would understand that this term means “any and all mutations that disrupt the functional expression of the endogenous gene.” Such traverse is not convincing. The claims should state with specificity, particularity, and clarity what Applicant regards as the invention.

##### **Rejections under 35 USC § 112, first paragraph**

The rejection of Claim 8 as being not enabled for any murine embryonic stem cell has been withdrawn in view of Applicants’ amendment of Claim 8 and argument.

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**Rejections under 35 USC § 101 and 35 USC § 112, first paragraph**

Claim 8 remains rejected under 35 USC 101, in the prior office action, as lacking any specific and substantial utility for reasons of record set forth in the office action of 8 September 2003.

Applicant's arguments filed 13 February 2004 have been fully considered but they are not persuasive.

Applicant argues in response that "Determining physiological function of the targeted gene is a major point of the present invention. If the function of the sequence was actually already known, why do the experiment?" Such response belies Applicant's utility is not substantial. A substantial utility defines a real world utility of the invention; utilities that require or constitute carrying out further research to identify or reasonably confirm a real world use are not substantial utilities (see utility guidelines, Federal Register, January 5, 2001, Vol. 66, No. 5, pp. 1092-99).

Applicant also argues that the cell lines provide a resource for mapping genes, can produce animals lacking a functional gene, in those instances that the protein is found to have a use it will have that use, large amounts of money spent on the genome databases, use in the discovery of *in vivo* function of human gene orthologs, Lasker awards for knockout mice, gene trap technology validated by another government agency, and the use in saving space and costs of mutated mice by keeping mutated ES cells (Applicants response, pp. 6-12). However, these issues do not constitute a specific and/or substantial utility. To wit, mapping genes is essentially an invitation to further experimentation; in those instances of finding a gene has a use makes it useful is certainly true, as it is axiomatic, but no specific and substantial use has yet been found

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because the function of a gene is not known; the accumulation and expenditure of large amounts of money on genome databases does not constitute the substantial utility of any specific genome sequence; research awards for technologies do not make such knowledge inherently substantial and specific for any specific gene; although NIH is another government agency, issuing requests for funding does not constitute utility as required by 35 USC 101. Moreover, the NIH is not the USPTO, and serves another function: the accumulation of knowledge, moreover, it is the gene trap technology of which Applicant discusses that is validated, not the specific genes trapped by such technology; and the space and expense saving, while specific for embryonic stem cells, is not substantial for Applicants specific ES cells, respectively.

Each of these “uses” constitute carrying out further research, and hence lacks a substantial utility. To wit, a substantial utility defines a real world utility of the invention; utilities that require or constitute carrying out further research to identify or reasonably confirm a real world use are not substantial utilities (see utility guidelines, Federal Register, January 5, 2001, Vol. 66, No. 5, pp. 1092-99).

### **CONCLUSION**

No Claim is allowed.

**THIS ACTION IS FINAL.**

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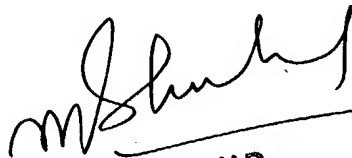
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**